

MEDICATION GUIDE

ACCUTANE Capsules (isotretinoin)

Read this Medication Guide every time you get a prescription or a refill for Accutane (ACK-you-tane). There may be new information. This information does not take the place of talking with your health care provider (provider).

What is the most important information I should know about Accutane?

Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics. However, Accutane can cause serious side effects. Before starting Accutane, discuss with your provider how bad your acne is, the possible benefits of Accutane, and its possible side effects, to decide if Accutane is right for you. Your provider will ask you to read and sign a form or forms indicating you understand some of the serious risks of Accutane.

Possible serious side effects of taking Accutane include *birth defects* and *mental disorders*

1. **Birth defects.** Accutane can cause birth defects (deformed babies) if taken by a pregnant woman. It can also cause miscarriage, premature birth, or death of the baby. Do not take Accutane if you are pregnant or plan to become pregnant while you are taking Accutane, or for 1 month after you stop taking Accutane. Also, if you get pregnant while taking Accutane, stop taking it right away and call your provider.

All females should read the section in this Medication Guide "What are the important warnings for female patients?"

2. **Mental problems and suicide.** Some patients, while taking Accutane or soon after stopping Accutane, have become depressed or developed other serious mental problems. Signs of these problems include feelings of sadness, irritability, unusual tiredness, trouble concentrating, and loss of appetite. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. No one knows if Accutane caused these behaviors or if they would have happened even if the person did not take Accutane.

All patients should read the section in this Medication Guide "What are the signs of mental problems?"

For other possible serious side effects of Accutane, see "What are the possible side effects of Accutane?" in this Medication Guide.

What are the important warnings for females taking Accutane?

You must not become pregnant while taking Accutane, or for 1 month after you stop taking Accutane. Accutane can cause severe birth defects in babies of women who take it while they are pregnant, even if they take Accutane for only a short time. There is an extremely high risk that your baby will be deformed or will die if you are pregnant while taking Accutane. Taking Accutane also increases the chance of losing the baby before it is born (miscarriage) and early (premature) births.

Female patients will not get their first prescription for Accutane unless there is proof from 2 tests that they are not pregnant. One test must be done on one of these 2 dates, whichever is later:

- the second day of your next period

- 11 days after you last had sexual intercourse without using birth control

You can get a prescription for Accutane only when the required testing shows you are not pregnant. Female patients cannot get monthly refills for Accutane, unless there is proof that they are not pregnant.

While you are taking Accutane, you must use effective birth control. You must use 2 separate effective forms of birth control at the same time for at least 1 month before starting Accutane, while you take it, and for 1 month after you stop taking it. You can either discuss effective birth control methods with your provider or go for a free visit to discuss birth control with someone else. Your provider can arrange this free visit.

You must use 2 separate forms of effective birth control because any method, including birth control pills and sterilization, can fail. Further, no one knows if Accutane lowers the effectiveness of birth control pills or injections (shots). There are only 2 reasons you would not need to use 2 separate methods of effective birth control:

- You have had your uterus removed by surgery (hysterectomy).
- You commit to complete abstinence. This means that you are absolutely positive that you will not have genital-to-genital sexual contact before, during, and for 1 month after Accutane treatment.

If you have sex without using effective birth control or miss your period, stop using Accutane and call your provider right away.

All patients should read the rest of this Medication Guide.

What are the signs of mental problems?

Tell your provider if, to the best of your knowledge, you or someone in your family has ever had any mental illness, including depression, suicidal behavior, or psychosis. Psychosis means a loss of contact with reality, such as hearing voices or seeing things that are not there. Also, tell your provider if you take medicines for any of these problems.

Stop using Accutane and tell your provider right away if you

- start to feel sad or have crying spells
- lose interest in your usual activities

- have changes in your normal sleep patterns
- become more irritable than usual
- lose your appetite
- become unusually tired
- have trouble concentrating
- withdraw from family and friends
- start having thoughts about hurting yourself/myself or taking your/my own life (suicidal thoughts)

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your provider about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Who should not take Accutane?

- Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment. Accutane causes birth defects. All females should read the section "What are the important warnings for females taking Accutane?" for more information and warnings about Accutane and pregnancy.
- Do not take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your provider if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, or any other important health problems. Tell your provider about any food or drug allergies you have had in the past. Your provider needs this information to discuss if Accutane is right for you.

How should I take Accutane?

- You will get a 1 month supply of Accutane at a time, to be sure you check in with your provider each month to discuss side effects.
- The amount of Accutane you take has been specially chosen for you and may change during treatment.
- You will take Accutane 2 times a day with food, unless your provider tells you otherwise.
- If you miss a dose, just skip that dose. Do not take 2 doses the next time.
- You should return to your provider as directed to make sure you don't have signs of serious side effects. Because some of Accutane's serious side effects show up in blood tests, some of these visits may involve blood tests.

What should I avoid while taking Accutane?

- Do not get pregnant while taking Accutane. See “What is the most important information I should know about Accutane?” and “What are the important warnings for females taking Accutane?”
- Do not breast feed while taking Accutane and for 1 month after stopping Accutane. We do not know if Accutane can pass through your milk and harm the baby.
- Do not give blood while you take Accutane and for 1 month after stopping Accutane. If someone who is pregnant gets your donated blood, her baby may be exposed to Accutane and may be born with birth defects.
- Do not take Vitamin A supplements. Vitamin A in high doses has many of the same side effects as Accutane. Taking both together may increase your chance of getting side effects.
- Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using Accutane and for at least 6 months after you stop. Accutane can increase your chance of scarring from these procedures. Check with your provider for advice about when you can have cosmetic procedures.
- Avoid sunlight and ultraviolet lights as much as possible. Tanning machines use ultraviolet lights. Accutane may make your skin more sensitive to light.
- Do not use birth control pills that have a low dose of progesterone (minipills). They may not work while you take Accutane.
- Do not share Accutane with other people. It can cause birth defects and other serious health problems.
- Do not take antibiotics with Accutane unless you talk to your provider. For some antibiotics, you may have to stop taking Accutane until the antibiotic treatment is finished. Use of both drugs together can increase the chances of getting increased pressure in the brain.

What are the possible side effects of Accutane?

Accutane has possible serious side effects

- Accutane can cause birth defects, premature births, and death in babies whose mothers took Accutane while they were pregnant. See “What is the most important information I should know about Accutane?” and “What are the important warnings for females taking Accutane?”
- Serious mental health problems. See “What is the most important information I should know about Accutane?”
- Serious brain problems. Accutane can increase the pressure in your brain. This can lead to permanent loss of sight, or in rare cases, death. Stop taking Accutane and call your provider right away if you get any of these signs of increased brain pressure: bad headache, blurred vision, dizziness, nausea, or vomiting. Also, some patients taking Accutane have had seizures (convulsions) or stroke.
- Abdomen (stomach area) problems. Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, and bowel (intestines). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your provider if you get severe stomach or bowel pain, diarrhea, rectal bleeding, yellowing of your skin or eyes, or dark urine.
- Bone and muscle problems. Accutane may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your provider if you plan vigorous physical activity during treatment with Accutane. Tell your provider if you develop pain. If a bone breaks, tell your provider you take Accutane. No one knows if taking Accutane for acne will reduce bone healing or stunt

growth.

- **Hearing problems.** Some people taking Accutane have developed hearing problems. It is possible that hearing loss can be permanent. Stop using Accutane and call your provider if your hearing gets worse or if you have ringing in your ears.
- **Vision problems.** While taking Accutane you may develop a sudden inability to see in the dark, so driving at night can be dangerous. This condition usually clears up after you stop taking Accutane, but it may be permanent. Other serious eye effects can occur. Stop taking Accutane and call your provider right away if you have any problems with your vision or dryness of the eyes that is painful or constant.
- **Lipid (fats and cholesterol in blood) problems.** Many people taking Accutane develop high levels of cholesterol and other fats in their blood. This can be a serious problem. Return to your provider for blood tests to check your lipids and to get any needed treatment. These problems generally go away when Accutane treatment is finished.
- **Allergic reactions.** In some people, Accutane can cause serious allergic reactions. Stop taking Accutane and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking Accutane and call your provider if you develop a fever, rash, or red patches or bruises on your legs.
- **Signs of other possibly serious problems.** Accutane may cause other problems. Tell your provider if you have trouble breathing (shortness of breath), are fainting, are very thirsty or urinate a lot, feel weak, have leg swelling, convulsions, slurred speech, problems moving, or any other serious or unusual problems. Frequent urination and thirst can be signs of blood sugar problems.

Serious permanent problems do not happen often. However, because the symptoms listed above may be signs of serious problems, if you get them, stop taking Accutane and call your provider. If not treated, they could lead to serious health problems. Even if these problems are treated, they may not clear up after you stop taking Accutane.

Accutane has less serious possible side effects

The common less serious side effects of Accutane are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. People who wear contact lenses may have trouble wearing them while taking Accutane and after therapy. Sometimes, people's acne may get worse for a while. They should continue taking Accutane unless told to stop by their provider.

These are not all of Accutane's possible side effects. Your provider or pharmacist can give you more detailed information that is written for health care professionals.

This Medication Guide is only a summary of some important information about Accutane. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any concerns or questions about Accutane, ask your provider. Do not use Accutane for a condition for which it was not prescribed.

Active Ingredient: Isotretinoin.

Inactive Ingredients: beeswax, butylated hydroxyanisole, edetate disodium, hydrogenated soybean oil flakes, hydrogenated vegetable oil, and soybean oil. Gelatin capsules contain glycerin and parabens (methyl and propyl), with the following dye systems: 10mg—iron oxide (red) and titanium dioxide; 20

mg—FD&C Red No. 3, FD&C Blue No. 1, and titanium dioxide; 40 mg—F&C Yellow No. 6, FD&C Yellow No. 10, and titanium dioxide.